Medical Coverage Policy | Subcutaneous ICD (S-ICD®) Implantable Cardioverter Defibrillator Insertion

EFFECTIVE DATE: 06|01|2015
POLICY LAST UPDATED: 05|19|2015

OVERVIEW

The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. A subcutaneous ICD (S-ICD®) has been developed that does not employ transvenous leads, with the goal of reducing lead-related complications.

Note: This policy applies to the insertion of a subcutaneous implantable cardioverter defibrillator only**.**

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

BlueCHiP for Medicare

Prior authorization is required for BlueCHiP for Medicare only and is obtained via the online tool for participating providers. See Related Policies section.

Commercial Products

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Subcutaneous implantable automatic defibrillators are covered for BlueCHiP for Medicare. Preauthorization is required and obtained via the online tool for participating providers.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

Commercial Products

Subcutaneous implantable automatic defibrillators are considered not medically necessary as there is insufficient peer-reviewed literature that demonstrates that the service is effective.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death.

Indications for ICD implantation can be broadly subdivided into (1) secondary prevention, i.e., their use in patients who have experienced a potentially life-threatening episode of VT (near sudden cardiac death); and (2) primary prevention, i.e., their use in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or VF.

The standard ICD involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator, which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized.

A totally subcutaneous ICD (S-ICD) has also been developed. This device does not employ transvenous leads and thus avoids the need for venous access and complications associated with the venous leads. Rather, the S-ICD uses a subcutaneous electrode that is implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous tissue of the chest wall.

S-ICD does not employ transvenous leads, with the goal of reducing lead-related complications. Evidence from nonrandomized controlled studies report success rates in terminating laboratory-induced VFs that are similar to transvenous ICD. However, there is scant evidence on comparative clinical outcomes of both types of ICD over longer periods of time. Case series report high rates of detection and successful conversion of VT, and inappropriate shock rates that are in the range reported for transvenous ICD. This evidence is not sufficient to determine whether there are small differences in efficacy between the two types of devices, which may be clinically important due to the nature to the disorder being treated. Also, the adverse event (AE) rate is uncertain, with variable rates of AEs reported in the available studies. At least one Randomized Control Trial (RCT) is currently underway to compare S-ICD with transvenous ICD. Because of the uncertainties around whether the S-ICD is as effective as transvenous ICD and uncertainties around the AE rates, the use of the S-ICD is considered not medically necessary for Commercial products.

CODING

Commercial Products

The following CPT codes effective on January 1, 2015 are not medically necessary:

33270	**33271**	**33273**
93260	**93261**	**93644**

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures
Removal of Not Medically Necessary Implanted Devices

PUBLISHED

Provider Update, July 2015
Provider Update, May 2015

REFERENCES

1. CMS.gov Centers for Medicare and Medicaid Services; National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4) http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110&ncdver=3&bc=AgAAgAAAAAAAAA%3d%3d&

2. CMS.gov Centers for Medicare and Medicaid Services; National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&

3. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. Eur Heart J. Jul 1 2014; 35(25):1657-1665. PMID 24670710

4. Gold MR, Weiss R, Theuns DA, et al. Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm. Aug 2014; 11(8):1352-1358. PMID 24732366

5. Kooiman KM, Knops RE, Olde Nordkamp L, et al Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: Implications for management. Heart Rhythm. 2014; 11(3):426-434. PMID

6. Groh CA, Sharma S, Pelchovitz DJ, et al. Use of an electrocardiographic screening tool to determine candidacy for a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm. Aug 2014; 11(8):1361-1366. PMID 24755323

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